



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,117	08/06/2001	William F. McKay	4002-2804	9544

7590 09/10/2004

Kenneth A. Gandy
Woodard Emhart Naughton Moriarty & McNett
Suite 3700
111 Monument Circle
Indianapolis, IN 46204-5137

EXAMINER

BONDERER, DAVID A

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/923,117	Applicant(s) MCKAY, WILLIAM F.	
	Examiner D. Austin Bonderer	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wironen et al.

Wironen discloses a bone paste filed on 9-16-98 comprising:

- A Carrier that thermally sets just above human temperature;
- Demineralized bone matrix;
- BIOGLASS;
- Hydroxyapatite;
- Cortical bone chips;
- Bone morphogenetic protein;
- Bone marrow extracts;
- Minerals are to compose anywhere from 0%-60% by weight;
- The carrier comprising 11-30% of the weight; and
- Wherein the composition is implanted into a living mammal.

Wironen lacks the ratios by volume, the specific particles sizes; or the claimed bone morphogenetic protein.

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to adjust the ratios of the carrier to other materials and particle size, since it has

Art Unit: 3732

been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the claimed bone morphogenetic protein, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

In respect to claims 18-26 and 29 are considered to be intended use of the composition. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ 1964 (1987).

Response to Arguments

3. Applicant's arguments filed 7-26-04 have been fully considered but they are not persuasive. The applicant claims that a porous particulate mineral in an amount of at least 20% and wherein the mineral is selected from a group of BIOGLASS and Hydroxyapatite.

4. In paragraph 29 of the reference it is stated:

Where present (ii) or like material is included to enhance the range of manipulable characteristics of strength and osteoinduction exhibited by the composition, and may comprise between about 0-60%, including about 40%, of the mass on a weight basis of the composition.

And in Paragraph 26 it states:

ii) bioactive glass ceramic, BIOGLASS.RTM., bioactive ceramic, calcium phosphate ceramic, hydroxyapatite, hydroxyapatite carbonate, coralline hydroxyapatite, calcined bone, cortical bone chips, cancellous bone chips, tricalcium phosphate, like material, or mixtures thereof; or

Art Unit: 3732

This disclosure clearly teaches the varying of the ratio between 0-60%. This encompasses the "at least 20%" limitation in the claims. The rejection is deemed proper.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Austin Bonderer whose telephone number is 703.306.5911. The examiner can normally be reached on Monday- Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703.308.2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3732

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

dab


PEDRO PHILOGENE
PRIMARY EXAMINER